Face masks to prevent community transmission of viral respiratory infections: A rapid evidence review using Bayesian analysis

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Abstract

Background: Face masks have been proposed as an important way of reducing transmission of viral respiratory infections, including SARS-CoV-2.

Objective: To assess the likelihood that wearing face masks in community settings reduces transmission of viral respiratory infections.

Methods: We conducted a rapid evidence review and used a Bayesian statistical approach to analysing experimental and observational studies conducted in community-dwelling children and adults that assessed the effectiveness of face mask wearing (vs. no face masks) on self-reported, laboratory-confirmed, or clinically diagnosed viral respiratory infections.

Results: Eleven RCTs and 10 observational studies met the inclusion criteria. The calculation of Bayes factors and cumulative posterior odds from the RCTs showed a moderate likelihood of a small effect of wearing surgical face masks in community settings in reducing self-reported influenza-like illness (ILI) (cumulative posterior odds = 3.61). However, the risk of reporting bias was high and evidence of reduction of clinically- or laboratory-confirmed infection was equivocal (cumulative posterior odds = 1.07 and 1.22, respectively). Observational studies yielded evidence of a negative association between face mask wearing and ILI but with high risk of confounding and reporting bias.

Conclusions: Available evidence from RCTs is equivocal as to whether or not wearing face masks in community settings results in a reduction in clinically- or laboratory-

confirmed viral respiratory infections. No relevant studies concerned SARS-CoV-2 or were undertaken in community settings in the UK.

Introduction

On March 11 2020, the global outbreak of the respiratory virus SARS-CoV-2, which causes COVID-19 (1), was declared a pandemic by the World Health Organisation (2). The primary route into the body for respiratory viruses such as SARS-CoV-2 is through the nose, eyes and mouth (the 'T-Zone') (3). Multipronged approaches involving both pharmacological (e.g. vaccination) and behavioural measures (e.g. hand washing, social distancing) are required to bring the reproductive number below 1 during respiratory virus epidemics (4–7). In public health interventions where certainty cannot be assured, it is often necessary to judge the benefits of interventions on their likelihood of benefit versus harm. This paper reports a rapid evidence review of studies evaluating the wearing of face masks in community settings on the likelihood of their leading to a reduction in the transmission of viral respiratory infections.

SARS-CoV-2 is spread through airborne droplets, and possibly in some cases aerosol, containing virions (8). Face masks of various types (e.g. surgical masks) filter droplets containing virus. However, they may not reduce transmission of the virus in community settings if they are not used correctly and may even increase transmission if they act as fomites or prompt other behaviours that transmit the virus such as face touching. For example, a face mask that has been worn for several hours becomes moist and acts as a potential source of contamination. Studies show that people touch their faces 15-23 times per hour on average (9,10), and this may mean that eyes and contaminated face masks are touched, spreading the virus. Several reviews have been undertaken on whether wearing face masks confers net benefit or harm (11–19). This rapid review aims to draw together the key evidence to date to try to establish the most comprehensive picture available. Given that policy has to be made on the basis of the likelihood of benefits versus harms rather than necessarily a high degree of confidence that a given policy will have the desired effect, it is important to focus on this likelihood. Therefore, this review includes the use of a Bayesian analysis to calculate cumulative posterior odds of the benefit of face mask wearing. It also widens the scope to consider issues such as adherence and adverse unintended consequences. We aimed to address the following research questions:

1. What is the likelihood that wearing face masks in community settings reduces

transmission of viral respiratory infections?
2. What is the quality of the evidence on this?
3. What is the level of adherence to face mask wearing?
4. Are there adverse unintended consequences of face mask wearing?

Method

Study design

The study protocol was pre-registered on the Open Science Framework (www.osf.io/bwcxp) and McMaster University's list of COVID-19 Rapid Evidence Reviews (https://www.nccmt.ca/knowledge-repositories/covid-19-evidence-reviews). We adopted acknowledged best practice for rapid evidence reviews (20). This involved limiting the search to published literature, having one reviewer extract data and another verify and presenting results as a narrative summary (21,22).

Eligibility criteria

Studies were included if they:

i. Were primary research studies using experimental (e.g. randomised controlled trial), quasi-experimental (e.g. pre- and post-test) and observational (e.g. case-control) study designs;
ii. Were conducted under free-living (as opposed to laboratory) conditions;
iii. Included a comparator (i.e. no face mask wearing);
iv. Were published in a peer-reviewed journal;
v. Were written in English;
vi. Involved as participants community-dwelling children and adults;
vii. Involved as intervention the wearing of commercial or hand-made face masks for preventing transmission of respiratory viruses;
viii. Recorded as outcome clinically or biochemically confirmed respiratory virus infections or self-reported symptoms consistent with respiratory virus infections such as influenza, respiratory syncytial virus, the common cold or SARS-CoV-2

Studies were excluded if they:

i. Involved as participants healthcare workers in healthcare settings

Search strategy

We identified articles through screening the reference lists of 10 recent literature reviews of non-pharmacological interventions to prevent transmission of respiratory viruses identified by the review team (11–19).

Selection of studies

Two reviewers (OP, DS) independently screened titles, abstracts and full texts against the eligibility criteria.

Data extraction

Data were extracted by one reviewer and verified by a second on: i) author (year), ii) pathogen/disease studied, iii) study design, iv) setting, v) population, vi) sample size, vii) type of face masks used, viii) intervention to improve adherence to face masks, ix) any adjunct intervention (e.g. hand sanitiser), x) predictors of effectiveness (e.g. perceived susceptibility), xi) adherence to face mask wearing, xii) reported proportion of sample with confirmed respiratory virus infection or self-reported symptoms of infection, and xiii) adverse unintended consequences (e.g. reduction in hand washing or other personal protective behaviours).

Evidence synthesis

Results from individual comparisons and outcomes in individual studies were tabulated in terms of adjusted odds ratios and 95% confidence intervals with the control group as the reference.

Following inspection of the results, it was decided to undertake Bayesian analyses to quantify the likelihood that face masks were effective. This involved calculating Bayes factors for each comparison and each outcome in each study, and then combining these Bayes factors to calculate cumulative posterior odds of a reduction in respiratory viral infections (23). Bayes factors represent the ratio of the likelihood that a given hypothesis (H1) is true versus another hypothesis (H0). In this case, H0 was that there was no difference between intervention and control conditions. Two different H1s were tested: 1) a small effect of a reduction of up to 10% in the odds of infection (adjusted odds ratio

of 0.90), and 2) a large effect of up to a 50% reduction in the odds of infection (adjusted odds ratio of 0.50). H1s were specified using a half-normal distribution starting on 0 with a standard deviation of the expected effects size (i.e. 10% or 50%) (24). Bayes factors ≥3 can be interpreted as substantial evidence for H1 versus H0. Bayes factors of ≤ 1/3 can be interpreted as evidence for H0 versus H1. Data yielding Bayes factors between 1/3 and 3 can be considered equivocal (23). Cumulative posterior odds were calculated for comparable studies (i.e. those with similar interventions and outcomes) by multiplying the Bayes factor together (23).

Quality appraisal

Two reviewers (OP, DS) used the GRADE (Grading of Recommendations, Assessment, Development and Evaluations) framework (25) to appraise the quality (low, moderate, high) of included studies.

Results

Study description

A total of 486 records were identified in the 10 literature reviews, 29 full texts were assessed, 21 of which met the inclusion criteria (see Figure 1).

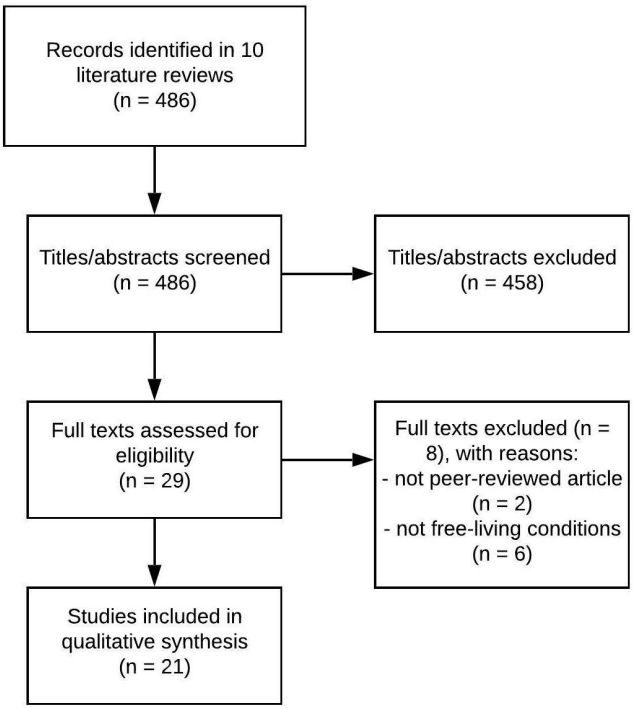

Figure 1. PRISMA flow diagram of included studies.

Study setting

The included studies were conducted in Saudi Arabia (26–32), China (including Hong Kong) (33–36), US (37–39), Japan (40,41), Germany (42), France (43), Australia (44), South Korea (45) and Thailand (46). No studies were found that were conducted in the UK.

Seven studies were conducted in households of index cases identified in primary or secondary care (33,35,36,43,44,46). Seven studies, all of which were conducted in Saudi Arabia, included participants on Hajj pilgrimage who were temporarily resident in communal tents or caravans (26–32). Five studies were conducted in the wider community, with participants recruited from universities (40), schools (41,45) and households (34,39). Two studies were conducted in university halls of residence (37,38).

Three studies were conducted during the 2009/2010 H1N1 epidemic (31,42,45) and one study was conducted during the 2002/2003 SARS epidemic (34); the remaining studies were conducted during non-epidemic conditions. No studies were found that were conducted within the SARS-CoV-2 pandemic (see Table 1).

Table 1. Characteristics of included studies (n = 21).

Lead author (year)	Country	Disease	Study design	Sample size
Aiello (2010)	US	Influenza-like illness	Cluster RCT	1297
Aiello (2012)	US	Influenza-like illness	Cluster RCT	1178
Al-Jasser (2012)	Saudi Arabia	Respiratory illness	Prospective cohort	1507
Balaban (2012)	Saudi Arabia	Respiratory illness	Prospective cohort	186
Barasheed (2014)	Saudi Arabia	Influenza-like illness	Pilot RCT	164
Canini (2010)	France	Influenza-like illness	Cluster RCT	105 index cases; 306 contacts
Choudhry (2006)	Saudi Arabia	Respiratory illness	Prospective cohort	1130
Cowling (2008)	Hong Kong	Influenza-like illness	Cluster RCT	122 index cases, 350 contacts
Cowling (2009)	Hong Kong	Influenza-like illness	Cluster RCT	407 index cases, 876 contacts
Deris (2010)	Saudi Arabia	Influenza-like illness	Cross-sectional	387
Emamian (2013)	Saudi Arabia	Respiratory illness	Nested case-control	338
Hashim (2016)	Saudi Arabia	Respiratory illness	Cross-sectional	468
Kim (2012)	South Korea	H1N1	Cross-sectional	7488
Larson (2010)	US	Influenza-like illness	Cluster RCT	2788
MacIntyre (2009)	Australia	Influenza-like illness	Cluster RCT	145 index cases, 286 contacts
MacIntyre (2016)	China	Influenza-like illness	Cluster RCT	245 index cases, 597 contacts
Shin (2018)	Japan	Common cold	Prospective cohort	265
Simmerman (2011)	Thailand	Influenza-like illness	Cluster RCT	465 index cases, 586 contacts
Suess (2012)	Germany	Influenza-like illness	Cluster RCT	84 index cases, 218 contacts
Uchida (2017)	Japan	Influenza-like illness	Prospective cohort	10,524
Wu (2004)	China	SARS	Case-control	94 cases, 281 controls

Study population

The majority of studies were conducted in adults, aged 16+ years (26,27,40,44,28–33,37,38). Seven studies were conducted in children and adults (34–36,39,42,43,46). Two studies were conducted in children only (41,45). Seven studies with participants on Hajj pilgrimage to Saudi Arabia included travelers from countries including Malaysia, Australia and the US (26–32).

Type and purpose of face mask use

Twelve studies reported outcomes related to the use of surgical masks (26,32,44,46,33,35–39,42,43). Nine studies did not record the type of mask used (27–31,34,40,41,45).

Ten studies employed observational designs and did not mandate who (e.g. index cases, contacts) was wearing the mask (27–32,34,40,41,45). Eleven studies employed cluster RCT designs, of which five studies instructed index patients and their contacts to use masks (26,35,36,42,46), three studies instructed asymptomatic participants to use masks (37–39), two studies instructed index cases to use masks (33,43) and one study instructed contacts of index cases to use masks (44).

Interventions to improve adherence to and safe disposal of face masks

No intervention to improve adherence to, or safe disposal of, mask use was provided to participants in the 10 observational studies (27–31,34,40,41,45). In the 11 RCTs, brief education was provided on the appropriate use of face masks and how to correctly take them on and off (26,33,46,35–39,42–44). Eight of the 11 RCTs provided adjunct interventions in the form of hand sanitizer (26,35–39,42) or instructions to wash hands (46).

Outcomes

Adherence to mask use

Studies operationalised self-reported adherence as hours/day of mask use

(26,37,38,43,46), the proportion of participants reporting mask use always or most of the time (vs. sometimes or never) (27,29,34,35,42), the proportion of participants reporting mask use as instructed (44) and the proportion of participants who reported mask use within 48 hours of symptom onset (39). Of studies explicitly commenting on the level of adherence to mask use, three study authors stated that adherence was 'good' (26,42,43) and three stated that it was 'poor' (35,39,44). Six studies did not report adherence to mask use (28,31,33,40,41,45).

Effectiveness of mask use

RCTs

The outcomes of included studies are reported in Table 2. One study found lower rates of self-reported symptoms of influenza-like illness (ILI) in the intervention compared with the control arm; however, in secondary analyses with laboratory-confirmed ILI, the rate of infection was less in the control arm than the intervention arm (26). Ten studies, two of which were pilot studies, found no statistically significant reduction in the rate of laboratory-confirmed or self-reported symptoms of ILI with face mask use in their primary analyses (33,35–39,42–44,46). In post-hoc (underpowered) analyses, however, significant reductions in rates of ILI were reported in six studies. Two studies found reduced rates of ILI in weeks 3-6 of the study period (totaling 6 weeks) (37,38). One study found significantly reduced odds of a household contact developing laboratory-confirmed ILI when the analysis was confined to participants who were allocated to the intervention or control arms within the first 36 hours of symptom onset in the index patient (36). One study found a significant reduction in the number of viral symptom episodes in a multivariable analysis following adjustment for age of the index case, education level of the caretaker and home crowding index (but not in a univariable analysis) (39). Two studies found a significant reduction in the rate of ILI in household contacts when, in a post-hoc analysis, they restricted the analysis to participants who received the face masks within 36 hours or two days of index case diagnosis or symptom onset, respectively (42,44). One study found a significant reduction in respiratory infections when restricting the analysis to the less stringent end-point of clinical respiratory illness (as compared with laboratory-confirmed infections or ILI) (33). The calculation of Bayes factors and cumulative posterior odds indicated that data showed a moderate likelihood of a small effect for the wearing of face masks on self-reported symptoms but evidence on clinically- or laboratory-confirmed ILI was equivocal (see Table 3).

Observational studies

Six observational studies found a significant reduction in self-reported respiratory virus symptoms in individuals who reported the use of face masks (as compared with no face mask use) (27,29,34,40,41,45). Four studies found no significant reduction in respiratory virus symptoms in individuals who reported the use of face masks (28,30–32). The calculation of Bayes factors and cumulative posterior odds indicated that data provided evidence for a large effect of the wearing of face masks on self-reported and clinically-confirmed ILI (see Table 3).

Table 2. Outcomes of included studies.

Lead author (year)	Sample size[1]	Adjusted odds ratio (95% CI)	Intervention arm(s)	Outcome(s)
RCTs				
Aiello (2010)	1042	1.00 0.90 (0.77-1.05)[2] 0.87 (0.73-1.02)[2]	Education on hand hygiene Face mask Face mask plus hand hygiene	Self-reported ILI
Aiello (2012)	828	1.00 1.10 (0.88-1.38)[2] 0.78 (0.57-1.08)[2]	No intervention Face mask Face mask plus hand hygiene	Self-reported ILI
Barasheed (2014)	164	1.00 **0.39 (0.16-0.96)[#3]**	No intervention Face mask	Self-reported ILI
Canini (2010)	296	1.00 0.95 (0.44-2.05)	No intervention Face mask	Self-reported ILI
Cowling (2008)	262	1.00 1.16 (0.31-4.34)	Education on healthy lifestyle Face mask	Laboratory confirmed influenza
Cowling (2009)	537	1.00 0.77 (0.38-1.55)	Education on healthy lifestyle Face mask plus hand hygiene	Laboratory confirmed influenza
Larson (2010)	2788	1.00 **0.82 (0.70-0.97)**	Education on infection control and prevention Face mask plus hand hygiene	Self-reported respiratory infection, ILI and laboratory confirmed influenza[4]
MacIntyre (2009)	286	1.00 1.11 (0.64-1.91) 2.51 (0.74-8.5)	No intervention Face mask[5] Face mask[5]	Self-reported ILI[6] Self-reported ILI[6] Laboratory confirmed influenza[6]
MacIntyre (2016)	597	1.00 0.65 (0.18-2.29)[7] 0.32 (0.03-3.11)[7] 0.97 (0.06-15.5)[7]	No intervention Face mask Face mask Face mask	Clinical respiratory illness[6] Clinical respiratory illness[6] Self-reported ILI[6] Laboratory confirmed respiratory infection[6]
Simmerman (2011)	885	1.00 1.16 (0.74-1.82)[3]	No intervention Face mask plus hand hygiene	Laboratory confirmed influenza
Suess (2012)	216	1.00 0.50 (0.21-1.19)	Education on infection prevention Combined arms (face mask and face mask plus hand hygiene)	Laboratory confirmed influenza

Table 2 cont.

Observational				
Al-Jasser (2012)	1507	1.00 **0.85 (0.72-1.00)**[8] **0.83 (0.70-0.97)**[8]	Face mask (never) Face mask (sometimes) Face mask (most of the time)	Self-reported respiratory infection
Balaban (2012)	143	1.00 1.42 (0.70-2.88)	No face mask Face mask	Self-reported respiratory illness
Choudhry (2006)	1027	1.00 **0.48 (0.35-0.66)**[8] **0.25 (0.19-0.32)**[8]	Face mask (never) Face mask (sometimes) Face mask (most of the time)	Self-reported respiratory infection
Deris (2010)	394	1.00 1.57 (0.98-2.52)[3]	No face mask Face mask	Self-reported ILI
Emamian (2013)	95	1.00 1.56 (0.56-4.35)[3]	No face mask Face mask	Clinically reported respiratory infection
Hashim (2016)	468	1.00 1.65 (0.79-3.47)	No face mask[5] Face mask	Self-reported respiratory illness
Kim (2012)	7449	1.00 1.02 (0.83-1.25)[3] **0.51 (0.30-0.88)**[3]	No face mask Face mask (irregular) Face mask (continuous)	Laboratory confirmed influenza
Shin (2018)	172	1.00 0.79 (0.41-1.54)[3]	No face mask Face mask	Self-reported viral respiratory symptoms
Uchida (2017)	10,524	1.00 **0.86 (0.78-0.95)**	No face mask Face mask	Clinically diagnosed influenza
Wu (2004)	100	1.00 **0.50 (0.20-0.90)**[3] **0.30 (0.20-0.60)**[3]	No face mask Face mask (sometimes) Face mask (always)	Self-reported SARS-like symptoms

[1] Sample size analysed; [2] Cumulative rate ratio; [3] Unadjusted odds ratio; [4] Composite end point; [5] Not surgical mask (e.g. towel, veil); [6] Listed as primary outcomes; [7] Unadjusted rate ratio; [8] Unadjusted relative risk; [#] Point estimate and confidence intervals derived by the review team from raw percentages; Numbers in bold face indicate statistical significance at p < .05

Table 3. Bayes factors and cumulative posterior odds for postulated small and large effects of face mask wearing in community settings.

Lead author (year)	Adjusted odds ratio/rate ratio (95% CI)*	Intervention arm	Outcome(s)	Bayes Factor: small expected effect (10% reduction)	Bayes Factor: large expected effect (50% reduction)	Cumulative posterior odds for small effect	Cumulative posterior odds for large effect
RCTs							
Aiello (2010)	0.90 (0.77-1.05)	Face mask	Self-reported ILI	1.81	0.49	1.81	0.49
Aiello (2012)	1.10 (0.88-1.38)	Face mask	Self-reported ILI	1.23	0.36	2.23	0.18
Barasheed (2014)	0.39 (0.16-0.96)	Face mask	Self-reported ILI	1.47	**4.62**	**3.27**	0.81
Canini (2010)	0.95 (0.44-2.05)	Face mask	Self-reported ILI	0.99	0.54	**3.24**	0.44
MacIntyre (2009)	1.11 (0.64-1.91)	Face mask[5]	Self-reported ILI[6]	1.04	0.5	**3.37**	0.22
MacIntyre (2016)	0.32 (0.03-3.11)	Face mask	Self-reported ILI	1.07	1.33	**3.61**	0.29
Cowling (2008)	1.16 (0.31-4.34)	Face mask	Laboratory confirmed influenza	1.01	0.79	1.01	0.79
MacIntyre (2009)	2.51 (0.74-8.5)	Face mask[3]	Laboratory confirmed influenza[4]	1.21	2.11	1.22	1.67
MacIntyre (2016)	0.97 (0.06-15.5)	Face mask	Laboratory confirmed respiratory infection[4]	1.0	0.9	1.22	1.50
MacIntyre (2016)	0.65 (0.18-2.29)	Face mask	Clinical respiratory illness	1.07	1.05	1.07	1.05
Aiello (2010)	0.87 (0.73-1.02)	Face mask plus hand hygiene	Self-reported ILI	2.52	0.86	2.52	0.86
Aiello (2012)	0.78 (0.57-1.08)	Face mask plus hand hygiene	Self-reported ILI	2.17	1.52	**5.47**	1.31
Cowling (2009)	0.77 (0.38-1.55)	Face mask plus hand hygiene	Laboratory confirmed influenza	1.14	0.84	1.14	0.84
Simmerman (2011)	1.16 (0.74-1.82)	Face mask plus hand hygiene	Laboratory confirmed influenza	1.14	0.55	1.30	0.46
Larson (2010)	0.82 (0.70-0.97)	Face mask plus hand hygiene	Self-reported respiratory infection, ILI and laboratory confirmed influenza[4]	**6.92**	**3.90**	**6.92**	**3.90**
Suess (2012)	0.50 (0.21-1.19)	Combined arms (face mask and face mask plus hand hygiene)	Laboratory confirmed influenza	1.33	2.33	1.33	2.33
Observational							
Al-Jasser (2012)	0.85 (0.72-1.00)	Face mask (sometimes)	Self-reported respiratory infection	**3.69**	1.49	**3.69**	1.49
Balaban (2012)	1.42 (0.70-2.88)	Face mask	Self-reported respiratory illness	1.21	1.08	**4.46**	1.61
Choudhry (2006)	0.48 (0.35-0.66)	Face mask (sometimes)	Self-reported respiratory infection	**35.6**	**>1000**	**158.95**	**1609.20**
Deris (2010)	1.57 (0.98-2.52)	Face mask	Self-reported ILI	1.88	**3.01**	**298.83**	**4843.69**
Hashim (2016)	1.65 (0.79-3.47)	Face mask	Self-reported respiratory illness	1.31	1.65	**391.46**	**7992.09**
Shin (2018)	0.79 (0.41-1.54)	Face mask	Self-reported viral respiratory symptoms	1.13	0.78	**442.35**	**6233.83**
Wu (2004)	0.50 (0.20-0.90)	Face mask (sometimes)	Self-reported SARS-like symptoms	1.48	**3.18**	**654.68**	**19823.58**
Kim (2012)	1.02 (0.83-1.25)	Face mask (irregular)	Laboratory confirmed influenza	0.78	0.17	0.78	0.17
Emamian (2013)	1.56 (0.56-4.35)	Face mask	Clinically reported respiratory infection	1.12	1.14	0.87	0.19
Uchida (2017)	0.86 (0.78-0.95)	Face mask	Clinically diagnosed influenza	**33.41**	**12.65**	**29.19**	2.45
Al-Jasser (2012)	0.83 (0.70-0.97)	Face mask (most of the time)	Self-reported respiratory infection	**5.57**	2.78	**5.57**	2.78
Choudhry (2006)	0.25 (0.19-0.32)	Face mask (most of the time)	Self-reported respiratory infection	**>1000**	**>1000**	**5570.00**	**2780.00**
Wu (2004)	0.30 (0.20-0.60)	Face mask (always)	Self-reported SARS-like symptoms	**5.48**	**>1000**	**30523.60**	**2780000.00**
Kim (2012)	0.51 (0.30-0.88)	Face mask (continuous)	Laboratory confirmed influenza	2.22	**9.8**	2.22	**9.80**

Note. * Referent = no intervention/education on infection prevention or healthy lifestyle.

Predictors of clinical outcomes

Four studies assessed whether self-reported adherence to mask use was a predictor of clinical outcomes, three of which observed a positive association (26,34,44) and one did

not (43). Two studies found reduced rates of infection when participants had been allocated to wear face masks within 36 hours of symptom onset (36,42). One study found that when the number of protective behaviours (e.g. hand washing, face mask use) was considered as a continuous variable, those engaging in a greater number of protective behaviours experienced shorter duration of respiratory illness (31).

Adverse unintended consequences

The majority of included studies did not report on whether there were unintended consequences. Two studies found that 50-75% of participants in the face mask arm reported pain/discomfort with mask use (43,44). One study found that those allocated to the face mask arm (as compared with those allocated to the face mask plus hand sanitiser or control arms) reported significantly less use of hand sanitiser (38). Four studies reported no significant differences in hand hygiene across study arms (35,36,39,46).

Quality appraisal

The quality ratings for each study are reported in Table 4.

Study limitations

Participant blinding to group allocation was not possible. Some studies reported contamination as participants in control arms decided to use face masks of their own accord (26,33,35,36). Use of self-reported (as opposed to laboratory-confirmed) respiratory virus symptoms or illness was commonplace. Overall, adherence to face mask use was poorly recorded.

Inconsistency of results

Only one of the 11 higher-quality studies employing RCT designs found a significantly reduced rate of ILI in their primary analyses. Both of the two higher-quality observational studies found a significantly reduced rate of clinically- or laboratory-confirmed ILI (41,45). Hence, the results are inconsistent across study designs and outcome assessments, with those employing more robust designs finding a non-significant effect of face mask use.

Indirectness of evidence

Only four of the included studies were conducted during an ongoing epidemic (31,34,42,45) and none was conducted during the SARS-CoV-2 pandemic. Only one of the 11 RCTs assessed transmission in the wider community (39); the remaining studies assessed viral spread to contacts who shared accommodation. A key concern during respiratory virus pandemics is transmission outside the household of index patients.

Imprecision

The RCT that found a significant effect of face mask use did not provide a confidence interval for the point estimate (26). One of the two higher-quality observational studies reported a narrow confidence interval, likely due to the large sample size (41). The remaining five observational studies with positive results reported wide confidence intervals (27,29,34,40,45), thus indicating poor precision of the effect of face mask use.

Reporting bias

Most analyses were not pre-registered, opening the possibility (especially in secondary analyses) of 'cherry picking' of findings.

Table 4. GRADE quality ratings for the included studies.

Lead author (year)	Study limitations	Indirectness of evidence	Imprecision	Reporting bias	GRADE rating
Aiello (2010)	Self-reported ILI; Pilot study	Non-epidemic conditions	Wide confidence interval reported	Potential 'cherry picking'	Low
Aiello (2012)	Self-reported ILI	Non-epidemic conditions		Potential 'cherry picking'	Moderate
Al-Jasser (2012)	Not RCT; Self-reported ILI	Non-epidemic conditions	Wide confidence interval reported		Low
Balaban (2012)	Not RCT; Self-reported ILI; Adherence not reported	Epidemic conditions	Wide confidence interval reported		Low
Barasheed (2014)	Self-reported ILI; Contamination	Non-epidemic conditions	Confidence interval not reported		Low
Canini (2010)	Self-reported ILI; Early termination	Non-epidemic conditions	Wide confidence interval reported		Low
Choudhry (2006)	Not RCT; Self-reported ILI	Non-epidemic conditions	Wide confidence interval reported		Low
Cowling (2008)	Laboratory-confirmed ILI; Contamination; Pilot study	Non-epidemic conditions	Wide confidence interval reported		Low
Cowling (2009)	Laboratory-confirmed ILI; Contamination	Non-epidemic conditions	Wide confidence interval reported	Potential 'cherry picking'	Moderate
Deris (2010)	Not RCT; Self-reported ILI; Adherence not reported	Non-epidemic conditions	Wide confidence interval reported		Low
Emamian (2013)	Not RCT; Clinically confirmed ILI	Non-epidemic conditions	Wide confidence interval reported		Low
Hashim (2016)	Self-reported ILI; Not RCT	Non-epidemic conditions	Wide confidence interval reported		Low
Kim (2012)	Not RCT; Laboratory-confirmed ILI; Adherence not reported	Epidemic conditions	Wide confidence interval reported		Moderate
Larson (2010)	Self-reported ILI	Non-epidemic conditions; masks not only provided to households with an index case	Wide confidence interval reported	Potential 'cherry picking'	Moderate
MacIntyre (2009)	Self-reported ILI	Non-epidemic conditions	Wide confidence interval reported	Potential 'cherry picking'	Moderate
MacIntyre (2016)	Self-reported ILI; Contamination; Adherence not reported	Non-epidemic conditions	Wide confidence interval reported	Potential 'cherry picking'	Moderate
Shin (2018)	Not RCT; Adherence not reported	Non-epidemic conditions	Wide confidence interval reported		Low
Simmerman (2011)	Laboratory-confirmed ILI	Non-epidemic conditions	Wide confidence interval reported		Moderate
Suess (2012)	Laboratory-confirmed ILI	Epidemic conditions	Wide confidence interval reported	Potential 'cherry picking'	Moderate
Uchida (2017)	Not RCT; Adherence not reported	Non-epidemic conditions	Narrow confidence interval reported		Moderate
Wu (2004)	Not RCT	Epidemic conditions	Wide confidence interval reported		Low

Discussion

Principal findings

This rapid review synthesised evidence from RCTs and observational studies on the effectiveness of face mask use to reduce transmission of respiratory viruses in community settings. This review widened the scope of available reviews on this topic to consider issues such as adherence and adverse unintended consequences of face mask wearing. One out of 11 RCTs and six out of 10 observational studies found a reduction in

the rate of self-reported or clinician diagnosed ILI in participants wearing face masks. The calculation of Bayes factors and cumulative posterior odds indicated that data from the RCTs and observational studies provided evidence of a small and large effect, respectively, of face mask wearing on self-reported ILI. Adherence and unintended consequences were rarely reported.

Strengths and limitations

An important feature of this review was the calculation of Bayes factors and cumulative posterior odds to examine the relative likelihood of there being an effect of wearing face masks versus no effect. A major limitation was that the search strategy may have missed relevant studies. Other major limitations relate to the studies themselves, including reliance on self-reported outcomes and reporting bias. In one study that included both self-reported and laboratory-confirmed infection, the former showed a benefit while the latter showed the opposite.

Implications for policy and practice

While the potentially biased self-reported outcomes from RCTs suggest a small benefit of face mask wearing, findings on clinically- and laboratory-confirmed infection remain equivocal. In addition, none of the studies concerned SARS-CoV-2 and none were conducted in the UK. All were in community settings that were different in many respects from the situation pertaining to SARS-CoV-2 in the UK. In light of this, judgements about the benefits or harms of wearing face masks will have to be made using a priori arguments rather than the data reviewed here: the scientific evidence should be considered equivocal. Such arguments should pay special attention to specific settings where the risk of infection is high and the opportunity for physical distancing is low (e.g. on crowded public transport), and to the need for education and training to maximise the potential benefits of wearing masks and mitigate the risk that they will transmit infection by acting as fomites.

Future research priorities

A standard protocol needs to be established for evaluating the benefits or harms of specific approaches to promoting face mask wearing in defined settings and populations. These protocols need to use objective measures of infection and take special precautions to minimise the risk of bias. They also need to include specific information on

what was done to promote the appropriate use of face masks and collect data on spill-over effects. Such a protocol is urgently needed for the COVID-19 pandemic but will continue to be relevant for future epidemics.

Conclusions

Evidence from RCTs is equivocal on whether face mask wearing in community settings reduces the transmission of clinically- or laboratory-confirmed viral respiratory infections. RCTs and observational studies have found an effect on self-reported symptoms, but this may be the result of reporting bias and confounding. No relevant studies concerned SARS-CoV-2 or were undertaken in community settings in the UK.

Conflicts of interest

None declared.

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